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10/719,612	11/21/2003	Fred H. Burbank	R0367-00105	3132

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/719,612

Applicant(s)

BURBANK ET AL.

Examiner

Brian Szmal

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 40-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 40-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/21/03; 5/24/05; 11-15-05

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_

### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: In line 1, "fro" should read as "for". Appropriate correction is required.
2. Claim 43 is objected to because of the following informalities: In line 2, ";" should read as ".". Appropriate correction is required.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 40-46, 48-59 and 62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 9-15 of U.S. Patent No. 6,331,166 B1. Although the conflicting claims are not identical, they

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are not patentably distinct from each other because the issued claims are written in a broader language than the current claims.

5. Claims 47, 60 and 61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7 and 9-15 of U.S. Patent No. 6,331,166 B1 in view of Burbank et al (6,699,206 B2). Burbank et al ('166) disclose an electrosurgical biopsy device, but fail to disclose the distal cutting tip is distally spaced away from the distal tip, and the use of an encapsulating instrument. Burbank et al ('206) disclose an electrosurgical biopsy means and further disclose the distal cutting tip is distally spaced away from the distal tip, and the use of an encapsulating instrument. Since both Burbank et al ('166) and Burbank et al ('206) disclose electrosurgical biopsy means, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the use of a spaced-apart distal cutting edge, and an encapsulating means, as per the teachings of Burbank et al ('206), since it would provide a means of effectively dissecting the tissue adjacent to the biopsy site as well as preventing the excised tissue from coming into contact with tissue when being removed.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a distal cutting edge, does not reasonably provide enablement for a curvilinear cutting surface. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification only discloses a distal cutting element on the biopsy device, and fails to explicitly disclose the shape of the cutting element.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Patterson et al (5,941,869).

Patterson et al disclose a means for removing stenotic material and further disclose a distal end adapted for entry into a patient's body; a cutting element disposed on the instrument, the cutting element being actuatable between a radially retracted position and a radially extended position relative to the axis, and being movable in the radially

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extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about the specimen; and the cutting element is rotatable at least in part about the longitudinal axis independent of the distal tip. See Column 27, lines 4-49; and Figures 38 and 39.

11. Claims 1, 40, 48, 50, 53, 54, 56-58 and 60-62 are rejected under 35 U.S.C. 102(e) as being anticipated by McGuckin, Jr. (6,280,450 B1).

McGuckin, Jr. disclose a means for performing breast surgery, and further disclose a distal end adapted for entry into a patient's body; a cutting element disposed on the instrument, the cutting element being actuatable between a radially retracted position and a radially extended position relative to the axis, and being movable in the radially extended position to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about the specimen; the first cutting element comprises a monopolar electrode; the first cutting element has a distal end secured to the elongated shaft and a proximal end which is configured to be moved longitudinally to radially move the first cutting element; the first cutting element is radially expandable to a plurality of radially extended positions; the first cutting element is rotatable at least in part about the longitudinal axis in a plurality of radially extended positions; an outer sheath disposed about the elongated shaft; the outer sheath is axially movable between a distal position covering at least in part the first cutting element and a proximal position uncovering at least part of the first cutting element; a driver unit for controlling radial expansion and retraction and rotation of the first cutting element; at least one encapsulation element; the encapsulation element is radially extendable from a radially retracted position to a

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radially extended position; and the first cutting element isolates a desired tissue specimen from surrounding tissue by defining a peripheral margin about at least part of the tissue specimen when the first cutting element is rotated at least in part about the longitudinal axis when electrically connected to an RF power source. See Figure 1, 4 and 5; Column 5, lines 65-67; and Column 6, lines 1-25, 45-49.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 42 and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) as applied to claim 40 above, and further in view of Hassler, Jr. (5,674,184).

McGuckin, Jr., as discussed above, discloses a means for performing a breast biopsy, but fails to disclose the distal tip has a second cutting element; the second cutting element is a monopolar electrode; the second cutting element is a bipolar electrode; the second cutting element secured to the distal tip is configured to receive RF energy; and the second cutting element is in part distally spaced away from the distal tip.

Hassler, Jr. discloses an electrosurgical trocar and further discloses the distal tip has a second cutting element; the second cutting element is a monopolar electrode; the second cutting element is a bipolar electrode; the second cutting element secured to the

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distal tip is configured to receive RF energy; and the second cutting element is in part distally spaced away from the distal tip. See Column 6, lines 22-29; and Column 7, lines 31-40.

Since both McGuckin, Jr. and Hassler, Jr. disclose means for placing a medical device in a body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of McGuckin, Jr. to include the means of an electrosurgical distal tip, as per the teachings of Hassler, Jr., since it would provide an alternative means to the sharpened distal tip for placing the device adjacent to the desired sample site.

14. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) as applied to claim 40 above, and further in view of Eggers et al (5,810,764).

McGuckin, Jr., as discussed above, discloses a means for performing a breast biopsy, but fails to disclose the first cutting element comprises a bipolar electrode.

Eggers et al disclose an electrosurgical cutting means and further disclose the use of a bipolar cutting electrode. See Column 12, lines 57-60.

Since both McGuckin, Jr. and Eggers et al disclose electrosurgical means for cutting tissue, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of McGuckin, Jr. to include the use of bipolar cutting elements, as per the teachings of Eggers et al, since it is well known in the art to utilize either monopolar or bipolar cutting elements for cutting tissue.



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15. Claims 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) as applied to claim 40 above, and further in view of Patterson et al (5,941,869).

McGuckin, Jr., as discussed above, discloses a means for performing a breast biopsy, but fails to disclose the first cutting element is configured to segment the specimen after it has been isolated from the surrounding tissue; and the first cutting element is configured to segment the specimen as it is being retracted from a radially extended position to a radially retracted position.

Patterson et al, as discussed above, disclose a means for removing stenotic material and further disclose the first cutting element is configured to segment the specimen after it has been isolated from the surrounding tissue; and the first cutting element is configured to segment the specimen as it is being retracted from a radially extended position to a radially retracted position. See Column 27, lines 4-49; and Figures 38 and 39.

Since both McGuckin, Jr. and Patterson et al disclose means for electrosurgically separating tissue, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of McGuckin, Jr. to include the ability to segment the tissue, as per the teachings of Patterson et al, since it would provide a means of dissecting the target tissue site for further analysis after removal from the body.

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16. Claims 55 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin, Jr. (6,280,450 B1) as applied to claim 40 above, and further in view of Kieturakis (5,794,626).

McGuckin, Jr., as discussed above, discloses a means for performing a breast biopsy, but fails to disclose the elongated shaft has an inner lumen for removing all or part of the tissue specimen from the body; and the driver unit further controls axial movement of the shaft and the axial movement of the sheath.

Kieturakis discloses an excisional biopsy apparatus and further discloses the elongated shaft has an inner lumen for removing all or part of the tissue specimen from the body; and the driver unit further controls axial movement of the shaft and the axial movement of the sheath. See Column 6, lines 13-19; and Column 8, lines 10-15.

Since both McGuckin, Jr. and Kieturakis disclose means for performing a biopsy, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of McGuckin, Jr. to include the use of an aspiration lumen and using a controller to control the axial movement of the shaft and sheath, as per the teachings of Kieturakis, since it would provide a means of acquiring the severed tissue sample and accurately controlling the movement of the device during the procedure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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